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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1492]

Two-Phased Chemistry, Manufacturing, and Controls Technical Sections; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #227) entitled "Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections." The purpose of this document is to provide recommendations to sponsors submitting CMC data submissions. For review efficiency, the Center for Veterinary Medicine (CVM) prefers that CMC information be submitted in a single technical section. However, there may be instances when a two-phased technical submission process is more beneficial to improve the overall time to drug approval. Sponsors may submit the phased CMC technical section as a single technical section or a two-phased technical section. This guidance describes the use of the two-phased technical section submission process.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather Longstaff, Center for Veterinary Medicine (HFV-145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0651, email: heather.longstaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (GFI #227) entitled "Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections." It is intended to provide recommendations to industry regarding CMC data submitted to CVM to support approval of a new animal drug or abbreviated new animal drug. As specified in the Animal Drug User Fee Amendments of 2013 (ADUFA III) and Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II) respective goals letters, the Agency agreed to develop guidance for a two-phased CMC technical section submission and review process by the end of fiscal year 2014.

The two-phased process allows for two separate CMC submissions, each with its own review clock, and each including complete appropriate CMC information that is available for

review at the time of submission. The draft guidance specifies the technical details of how the process works, the review clocks, the information that is appropriate for each technical section submission, and the possible review outcomes. The guidance also includes CVM's recommendations for meetings between the Division of Manufacturing Technologies and the sponsor during this process to ensure concurrence with the approach used for the CMC technical section.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in this guidance have been approved under 0910-0032 and 0910-0669.

IV. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: October 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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